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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

MERRIAM, A

ART UNIT PAPER NUMBER

1511

#8

DATE MAILED: 06/24/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on July 17, 1996
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-3, 70-92 is/are pending in the application.
- Of the above, claim(s) 1-3, 85 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 70-84, 86-92 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☒ Claim(s) 1-3, 70-92 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5, 6, 7
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGE

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15. The Examiner acknowledges receipt of the applicants' Information Disclosure Statements (IDS). The July 17, 1996 IDS is missing the Kunzler reference. Furthermore, no date has been provided for this reference. This reference would not be otherwise available to the Examiner and cannot be made of record without a date. Please supply the reference and a date for it to the Examiner.

16. Newly submitted claims 1-3 and 85 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 1-3 85, which depend upon claim 1, are drawn to a polymeric lens which is related to the remaining claims 70-84 and 86-92 as a combination and subcombination. In the instant case, the combination of the elected claims 70-84 and 86-92 does not require the particular polymeric oxy perm or ionic permeable material. Moreover, the subcombination of claims 1-3 and 85 has separate utility as a wound healing or drug delivery device in the ocular environment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-3 and 85 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

17. The Examiner acknowledges receipt of the applicants' preliminary amendment filed on July 17, 1997. The preliminary amendment has largely been entered on the record, with one exception:

Claims 1-3 have not been cancelled. Page 99 of the specification, which page contains claims 1-3, is missing. Please file a new copy of page 99, including claims 1-3, along with a request for their cancellation.

The Examiner also suggests that the applicants cancel claim 85, which is dependent upon claim 1. Alternatively, the applicants might consider putting claim 85 in with the group of claims presently elected, claims 70-84 and 86-92.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

19. Claim 84 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention. The concept of short relaxation time is not defined in the specification, which rather refers to stress relaxation. One of ordinary skill in the art cannot discern a correlation between stress relaxation and short relaxation time, since stress relaxation requires only stress and then an unstressed condition, which does not speak of a time. Further, one of ordinary skill in the art cannot discern the concept of what a short relaxation is. Further clarification in the specification and in claim 84 is required.

20. Claims 86-87 and 89-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The rejected claims recite ion permeability and ion diffusion coefficients, without specifying the ion in question. The coefficients presently claimed require recitation of a specific ion since not all ions diffuse at the same rate and since all ions have different potentials in solution. Please refer to the Nernst equation, which equation relates to the solution potential of ions in relation to their concentration and electrode potential.

Further clarification is required.

21. Claims 70-84 and 86-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while

being enabling for specific ophthalmic lenses which contain ionic and oxygen permeable polymers, or polymer segments, which lenses are made by a process which includes polymerization in the absence of oxygen, followed by extraction and/or degassing, does not reasonably provide enablement for an ophthalmic lens, in general, which recites merely oxygen permeable and ion or water permeable properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The present specification at pages 61-62 requires the polymerization in the absence of oxygen, followed by extraction or degassing in order to give the presently claimed permeability properties. Further, the applicants' position that the presently claimed invention is bona fide in condition for allowance necessitates the present rejection: Applicants maintain that the prior art does not give the presently claimed oxygen and ion permeability properties, while at the same time the prior art reads upon specific composition embodiments presently specified in the present specification at pages 26-58. In other words, the applicants' invention must recite combinations of elements more than mere compositions in order to meet the presently claimed functions. The law requires that the applicants claim and disclose in a distinct fashion the required combinations necessary to arrive at

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the ion and water and oxygen permeability properties presently claimed.

22. Claims 70-84 and 86-92 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Lai, U.S. 5,310,779, McGee et al., U.S. 5,387,663, or Yokoyama et al., U.S. 5,346,946, the Yokoyama reference of record.

Lai discloses hydrogel oxygen-permeable lenses, wherein the lenses comprise copolymers which are copolymerized in an oxygen-free atmosphere, and further wherein the copolymers comprise siloxane macromonomers of urethane acrylates or polyol acrylates, the monomers being difunctional and being copolymerized with ion-permeable polymer giving methacrylic acid ester polymers from hydroxyethyl methacrylate (HEMA), various acrylamides or NVP, wherein yet still further the siloxane macromonomers are copolymerized with cross-linkers such as polyurethane-siloxane bis(meth)acrylates. Another preferred hydrogel is a fluoroether-modified methacrylate capped polysiloxane, copolymerized with a methacrylate and a methacrylamide or NVP (N-vinyl pyrrolidone). See Lai at the Abstract, col. 4, lines 3-14 and 24-40, col. 5, lines 42-56, col. 6, lines 53-66, col. 7, lines 27-69, col. 8, lines 1-32 and 42-69, col. 9, lines 1-69, col. 10, lines 1-69, col. 11, lines 1-13 and 45-65 and col. 12, lines 13-17. Specific low water

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content, high oxygen permeability hydrogels are shown at Example 37 on cols. 19-20, Example 41 on col. 21, Examples 40-53 on col. 23 and Example 16 on col. 17. Lai discloses hydrogels which give high wearability and comfort, including extended wear properties, as is shown at col. 3, lines 55-65. Lai reads upon the presently claimed oxygen permeability.

McGee discloses oxygen permeable contact lenses which are wettable hydrogels, which lenses comprise siloxane macromonomers from urethane-functional polysiloxane bis(meth)acrylates, which are cross-linked and copolymerized with hydrophilic acrylic monomers such as HEMA, acrylamides, and further wherein the cross-linking agents may comprise polysiloxane-bisurethane dimethacrylates. See the Abstract, col. 1, lines 1-20 and 48-65, col. 2, lines 23-37, col. 5, lines 30-45 and 55-60, col. 6, lines 5-20 and 53-68, col. 7, lines 35-40, col. 8, lines 5-15 and 38-50 and Table I on col. 10, as well as Table II on col. 11. Note that McGee discloses polymerization under a nitrogen blanket, followed by extraction and hydration. See Example A at the bottom of col. 8 and the passage at col. 8, lines 5-15. McGee discloses the presently claimed oxygen permeability, as well as the presently claimed long wear period and minimal damage to corneal tissue.

Yokoyama discloses high oxygen permeability contact lenses which are water-swellaable hydrogels, wherein the lenses

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comprise siloxane acrylates copolymerized with cross-linkers and other methacrylic monomers, the siloxanes comprising urethane siloxane di(meth)acrylates, such as those shown in Example 1, which are copolymerized with the presently specified amounts of hydrophilic monomers, TRIS monomers and ethylene glycol dimethacrylate cross-linkers. See especially Examples 6 and 8 on Table 1 at cols. 15-16 of Yokoyama. See also Yokoyama at the Abstract, col. 1, lines 1-22, col. 5, lines 43-50, Example 1 at cols. 13-14, col. 14, lines 45-55 and col. 16, lines 25-35. See also Example 25 in Table 2 at cols. 17 and 18. Yokoyama discloses the presently claimed oxygen permeability. Further, the Yokoyama Examples read upon the exemplified materials in the present specification.

The presently claimed extended wear, oxygen and ion permeability, modulus and relaxation time properties all inherently ensue from Yokoyama, Lai and McGee. The rationale is that all references show oxygen and ion permeable materials which read upon exemplary materials in the present specification. Furthermore, each of Lai and McGee shows specific processing parameters of oxygen-free polymerization followed by extraction or degassing. Thus, these references read upon all the statutory elements presently claimed or specified. Further, they show all of the presently claimed oxygen permeability properties and specify extended wear or wearer comfort along with limited

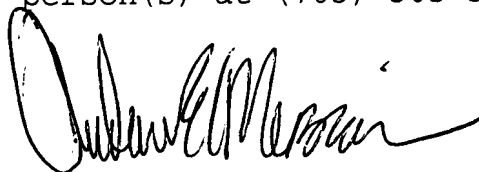


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corneal damage. By chemical identity, as well as process identity, the functional result of each of Yokoyama, Lai and McGee falls within the scope of the presently claimed functions and properties.

It would at least have been obvious in view of Lai, McGee or Yokoyama to maximize extended wear, minimize corneal damage, maximize ion and oxygen permeability, while at the same time fashioning a feasible lens. The rationale is that one of ordinary skill in the art knows that oxygen permeability and wettability increase wearer comfort, minimize corneal swelling and give properties which include desirable water permeability and ion permeability. Further, the materials shown in Yokoyama, McGee and Lai all read upon exemplified materials shown in the present specification. One would expect the same materials to give the same properties, when processed in the presently exemplified manner.

23. Any inquiry concerning this communication should be directed to Examiner Merriam at telephone number (703) 308-4353 or Supervisor Vasu Jaganathan at (703) 306-2777. Fax inquiries should be directed to either person(s) at (703) 305-5433.



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